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One-year Clinical Outcome after Primary Stenting for Trans-Atlantic Inter-Society Consensus (TASC) C and D Femoropopliteal Lesions (The STELLA "STEnting Long de L'Artère fémorale superficielle" Cohort)

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WHAT THIS PAPER ADDS?

- Currently, endovascular treatment of long femoropopliteal lesions as a first-choice treatment remains controversial. Despite a high technical success rate, little data are available on the clinical benefit for patients over time. In the present study we prospectively assessed the safety and the efficacy of primary stenting for TASC C and D femoropopliteal lesions. We found that sustained clinical improvement at mid-term was high. Nevertheless, the necessity of secondary procedures due to in-stent restenosis and thrombosis makes narrow surveillance mandatory. Therefore, our results contribute to further support the use of primary stenting for TASC C and D femoropopliteal lesions.

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ABSTRACT

Objective: The study aims to evaluate the safety and the efficacy of primary stenting for Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease (TASC) C and D femoropopliteal lesions.
Design: Prospective cohort study.
Methods: Patients with TASC C and D *de novo* femoropopliteal lesions were treated with the same endovascular technique by implanting a primary nitinol self-expanding stent (LifeStent®, Bard Peripheral Vascular, Tempe, AZ, USA). Patients were included in a single-centre registry and prospectively followed up. The primary end point was primary sustained clinical improvement after 12 months. Secondary end points were secondary sustained clinical improvement, primary and secondary patency rates, freedom from target lesion revascularisation (TLR), freedom from target extremity revascularisation (TER) and stent fracture rate.
Results: We enrolled 58 patients (62 limbs) suffering from either claudication (40.3%) or critical limb ischaemia (59.7%). Lesions were either TASC C (62.9%) or TASC D (37.1%). Median length of the treated segment was 220 ± 160 mm. The mean number of stents was 2.2. Mean follow-up was 17 months, with one patient lost to follow-up. At 1 year, the primary end point was 68.6% while secondary sustained clinical improvement was 82.6%. Freedom from TLR and TER rates were 81.1% and 96.3%. Primary and secondary patencies were 66% and 80.9%. One-year primary and secondary sustained clinical improvement rates were 76.7% ± 7.2 for TASC C and 46.3% ± 11.1 for TASC D ($p = 0.03$) and 87.6% ± 5.9 for TASC C and 67.3% ± 11.3 for TASC D ($p = 0.09$), respectively. The ankle–brachial pressure index increased from

Abbreviations: ABI, ankle–brachial index; CLI, critical limb ischaemia; DSA, digital subtraction angiography; IC, intermittent claudication; ISR, in-stent restenosis; MACE, major adverse clinical event; PAD, peripheral arterial disease; PSV, peak systolic velocity; TASC, Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease; TER, target extremity revascularisation; TLR, target lesion revascularisation.

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0.58 to 0.94 ($p = 0.001$) at 1 year and the incidence of in-stent restenosis (ISR) was 19.3%. Stent fracture and disconnection rate was 17.7%.
Conclusions: Primary stenting of TASC C and D lesions appears to be safe and efficient given the high-sustained clinical improvement and the low rate of ISR observed in our study. Endovascular treatment of such long and severe lesions exposes to high rate of stent fractures, which should not be a concern given their low clinical impact.
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The Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease (TASC) was published in 2007.[1] In its revised stratification for femoropopliteal lesions, TASC II included more severe disease levels than TASC I and recommended endovascular repair for type A, B and C (with qualifications). However, endovascular repair remains commonly indicated in limited lesions shorter than 150 cm whereas bypass surgery is recommended to treat extensive disease with long lesions and critical limb ischaemia (CLI).

Recent advances in endovascular techniques have led to widespread applicability of endovascular repair for more severe femoropopliteal lesions. Even though lesions are more distal and longer, the technical success does not seem to be altered. Successful recanalisation of TASC C and D lesions exceeds 80%.[2,3] In addition, the use of new techniques and devices such as retrograde approach and re-entry catheters improves the technical success rates following failed initial procedure.[2] According to some authors, failure of endovascular repair does not preclude the possibility of infrainguinal bypass.[4] Thus, the use of primary stenting to treat femoropopliteal occlusive lesions has shown the most promising outcomes.[5] However, primary stenting for longer femoropopliteal lesions is controversial because of the high risk of stent fracture.

Newer generations of longer nitinol self-expanding stents could allow endovascular treatment of longer femoropopliteal lesions thanks to their resistance to compression and fracture in this tortuous physical environment.[6] The purpose of the Stenting long de l'artère fémorale superficielle (STELLA) study was to evaluate prospectively the safety and the efficacy of primary stenting using LifeStent® (Bard Peripheral Vascular, Tempe, AZ, USA) to treat femoropopliteal TASC C and D lesions.

Methods

Experimental design

STELLA is a follow-up single-centre study cohort in which patients were referred for peripheral arterial disease (PAD) and presented with *de novo* femoropopliteal TASC C and D lesions longer than 15 cm. Patients were enrolled between November 2008 and October 2009. Endovascular therapy was considered a first intention treatment. Inclusion and exclusion criteria are summarised in Table 1. Patients had either one or two limbs treated. The protocol was approved by the local ethics committee and all patients gave informed consent.

Endovascular procedures

All procedures were performed by vascular surgeons. Patients were examined preoperatively by an anaesthesiologist. Local anaesthesia with conscious sedation was indicated unless general anaesthesia was required. Access to the culprit lesion was achieved either by way of an over-the-aortic-bifurcation approach with the use of a dedicated 6F-long sheath (45 cm) (Destination®, Terumo, St Quentin, France) or via antegrade approach with the use of a 6F sheath (Destination®, Terumo, St Quentin, France). After sheath placement, an intravenous bolus of 50 UI kg^{-1} of heparin was administered. Stenotic lesions were crossed in an intraluminal fashion and occlusions were recanalised with a hydrophilic 0.035-inch guide wire and a balloon catheter (Optapro®, Cordis, Issy, France). An intentional plane was created in the proximal patent artery by forming a loop at the end of the guide wire. The looped guide wire and the balloon catheter were then forcefully advanced across the occlusion. The true lumen re-entry was indicated by a subtle release of wire resistance near the distal portion of arterial occlusion. Distal re-entry was ensured after withdrawal of the guide wire by contrast media injection through the balloon lumen catheter. No re-entry device was used. Primary stenting was preferably performed unless predilation with a 3-mm balloon was necessary because of highly calcified lesions. The stent dimensions were chosen by visual estimation to fit vessel diameter at best with a length exceeding the lesion length by 5–10 mm proximally and distally. The maximal available length of stent was 170 mm. Lesions were treated with as few stents as possible. Adjacent stents overlapped by 1 cm. We used the self-expandable LifeStents® (Bard Peripheral Vascular, Tempe, AZ, USA) of either 6 or 7 mm in diameter. Stents were routinely post-dilated to ensure optimal extension and apposition. The balloon dimension (Optapro®, Cordis, Issy, France) was chosen so that the nominal diameter is 1 mm narrower than the vessel diameter to reduce medial damage[7] and so that the balloon length does not exceed that of the stent. The technical result of the procedure was assessed by digital subtraction angiography (DSA). Every associated inflow or outflow lesions suspected to be involved in the disease were treated during the same procedure. Significant aspect of the lesion was assessed by the surgical team according to preoperative findings (magnetic resonance imaging (MRI), angio-computed tomography (CT) scan and duplex ultrasonography (US)), clinical stage of the disease (CLI vs. intermittent claudication (IC)) as well as to intra-operative findings (DSA). Groin closure was accomplished via manual compression

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Age ≥ 50-years • Symtomatic patients according Rutherford stages 3, 4, 5 and 6 • *De novo* atheromatous femoropopliteal occlusive disease >15 cm in length • TASC C–D femoro-popliteal lesions according the TASC II guidelines • Adequate femoro-popliteal inflow and outflow either pre-existing or successfully re-established (outflow defined as patency of at least one infragenicular artery) • Successful crossing of the target lesion, inflow and outflow lesions with a guide wire • Written informed consent • Patient belongs to the French health care system	• Restenosis • No atheromatous disease • Asymptomatic lesion • Acute ischaemia or arterial thrombosis • Lesion within or adjacent to an aneurysm • Patient enrolled in another trial • Refusing patient • Pregnancy • Known allergies to heparin, aspirin, other anti-coagulant/ antiplatelet therapies • No written informed consent • Life expectancy < 1 year

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